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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,485	03/08/2001	Erin B. Dickerson	WARF-0003	4744

26259 7590 03/26/2003

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EXAMINER

SEHARASEYON, JEGATHEESAN

ART UNIT

PAPER NUMBER

1647

DATE MAILED: 03/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/801,485	DICKERSON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jagatheesan Seharaseyon, Ph.D.	1647	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 January 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-9 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 27-37 drawn to a fusion protein comprising a mammalian interleukin-12 operably linked to an RGD-containing peptide, classified in class 514, subclass 2, for example.
  - II. Claims 4-6, drawn to a nucleic acid sequence encoding a fusion protein, vectors, and host cells comprising same, classified in class 435, subclass 320.1, for example.
  - III. Claim 7, drawn to a method for inhibiting growth of angiogenic endothelial cells and  $\alpha v \beta 3$  positive tumor cells, classified in class 514, subclass 2, for example.
  - IV. Claim 8, drawn to a method for decreasing toxic side effects associated with interleukin-12 administration in a mammal, classified in class 514, subclass 2, for example.
  - V. Claim 9, drawn to a method for treating cancer in a mammal, classified in class 514, subclass 2, for example.

2. The inventions are distinct, each from the other because of the following reasons:
3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions III, IV, VI, and V are directed to methods that are distinct

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both physically and functionally, and are not required one for the other. Invention III requires search and consideration of inhibiting growth of angiogenic endothelial cells, which is not required by any of the other Inventions. Invention IV requires search and consideration of decreasing toxic side effects associated with interleukin-12 administration in a mammal, which is not required by any of the other Inventions. Invention VI requires search and consideration of treating cancer, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions I and II are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. The peptide of Invention I can be prepared by processes which are materially different from the nucleic acid, vectors, and host cells of Invention II, such as by chemical synthesis, or by isolation and purification from natural sources. Although the nucleic acid, vectors, and host cells of Invention II can be used to obtain the peptide of Invention I it can also be used in materially different methods, such as in various diagnostic (e.g., *in situ* hybridizations), or therapeutic methods.

5. Inventions I and each of III, IV, and V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the processes for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product as claimed can be used in a

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materially different process of using that product. The peptide of Invention I can be used to isolate receptors.

6. Inventions II and each of III, IV, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of III, IV, and V are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, and V do not recite the use or production of the nucleic acid, vectors, and host cells of Invention II.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

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***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jegatheesan Seharaseyon, Ph.D.** whose telephone number is **703-305-1112**. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
March 20<sup>th</sup>, 2003

  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**